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Seventh United Nations Conference to Review All Aspects of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices

Geneva, 6–10 July 2015

Item 6 (b) of the provisional agenda

Consideration of proposals for the improvement and further development of the Set, including international cooperation in the field of control of restrictive business practices

The role of competition in the pharmaceutical sector and its benefits for consumers

Note by the UNCTAD secretariat

Executive summary

Competition policy aims to make markets work for consumers through its core elements: enforcement and advocacy. Nevertheless, when pursuing better access to products, measures against anticompetitive behaviour in the pharmaceutical sector may not be the best starting point, in comparison with other areas of law. As a relatively underdeveloped yet promising mechanism for doing so, competition policy should be given greater prominence for its potential to complement efforts in this area. This report addresses some of the main competition problems in the pharmaceutical industry today. It gives examples from various jurisdictions on the benefits of competition enforcement for consumers and recommends some measures to enhance competition advocacy in the pharmaceutical industry.

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Introduction

1. The pharmaceutical industry plays an important role in improving global health care. Three of the eight Millennium Development Goals call for specific health care improvements by 2015. However, around two billion people worldwide have inadequate access to essential medicines and vaccines, or none at all.

2. Disease and poverty are interdependent. People are often sick because they are poor. They may become poorer because they are sick and sicker because they are poorer. Yet, many of the illnesses affecting people living in poverty can be prevented, alleviated or cured with a relatively small number of essential medicines if they are available at affordable prices.

3. Limited public health services budgets and steadily increasing expenses slow economic growth.[1] Meanwhile, drug expenditures keep rising. In 2011, the total pharmaceutical bill across countries of the Organization of Economic Cooperation and Development (OECD) was about $800 billion. In 2013, global pharmaceutical sales reached an all-time high of approximately $980 billion and are expected to rise beyond one trillion dollars by 2015.[2]

4. Competition is important because it compels industry to provide higher quality goods and services at lower prices. In the pharmaceutical industry, competition can motivate brand companies to create new and improved medicines and encourage generic companies to offer less expensive alternatives.

5. On average, pharmaceutical spending accounted for 1.5 per cent of gross domestic product (GDP), with about 0.8 per cent of GDP publicly financed, and the remainder, from private sources.[3] Competition policy can improve both consumer and government access to affordable pharmaceuticals through two core elements: enforcement and advocacy.

6. Throughout much of the world, however, administrative regulation, rather than competition policy, dominates efforts to afford consumers and governments adequate access to affordable drugs.

7. Although strict administrative regulation has stabilized prices for certain drugs, it has also deepened competition enforcement challenges in the private sector. Also, competition advocacy contributes towards a more transparent, efficient and consumer-friendly administrative regulation environment. Competition policy is important in both the public and private sectors and should be given greater prominence to complement other efforts in this area.

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[1] Federal Antimonopoly Service of Russia [the Russian Federation], 2013, Results of the Assessment of Pharmaceuticals Affordability on Basis of the Analysis of Consumer Prices and Price Setting for Pharmaceuticals in the Russian Federation (Federal subjects included) and on Comparable Markets of other Countries, Comprising the CIS [Commonwealth of Independent States], European Union and BRICS [Brazil, the Russian Federation, India, China and South Africa]. Available at http://en.fas.gov.ru/netcat_files/560/719/h_16877705280114952718 36c96cbf82ec. accessed 29 September 2014.

[2] Thomson Reuters, 2014, Thomson Reuters Annual Pharmaceutical Factbook projects industry's sales will reach $1 trillion in 2014, available at http://thomsonreuters.com/en/press-releases/2014/thomson-reuters-annual-pharmaceutical-factbook-projects-industrys-sales-will-reach-1-trillion-in-2014.html, accessed 27 April 2015.

[3] OECD, 2013, *Health at a Glance 2013: OECD Indicators*, OECD Publishing, available at http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf, accessed 28 October 2014.

8. This report addresses some competition problems in the pharmaceutical industry, gives examples from various jurisdictions on how competition enforcement benefits consumers and recommends measures to enhance competition advocacy in the pharmaceutical industry.

9. This report draws from recent research and international reports in this area, such as reports by UNCTAD, the United Nations Office for Project Services, the World Intellectual Property Organization, the World Health Organization (WHO), OECD and the European Union.

I. Competition problems

10. In general, the low elasticity of demand associated with in the pharmaceutical industry can be attributed to the must-have nature of many drugs, owing to the lack of alternatives and regulatory requirements on the range of the products that providers must offer and insurers must cover. The supply of brand drugs is characterized by considerable market power because of the presence of patents to reward the high investment in research and development that brand drug companies maintain is necessary to bring new drugs to market. Notwithstanding the rise of generic companies in emerging countries leading to more robust competition, there has been no significant change in the ranking of the leading pharmaceutical companies. This creates competition concerns, and prices continue to rise owing to these market features.

Table 1
Top 10 pharmaceutical companies by revenue

	2013	*2012*	*2011*	*2010*
1	Pfizer (United States of America)	Pfizer	Pfizer	Pfizer
2	Novartis (Switzerland)	Novartis	Novartis	Novartis
3	Roche (Switzerland)	Merck and Co.	Merck and Co.	Sanofi
4	Merck and Co. (United States)	Sanofi	Sanofi	Merck and Co.
5	Sanofi (France)	Roche	Roche	GlaxoSmithKline
6	GlaxoSmithKline (United Kingdom of Great Britain and Northern Ireland)	GlaxoSmithKline	GlaxoSmithKline	Roche
7	Johnson and Johnson (United States)	AstraZeneca	AstraZeneca	AstraZeneca
8	AstraZeneca (United Kingdom)	Johnson and Johnson	Johnson and Johnson	Johnson and Johnson
9	Lilly (United States)	Lilly	Lilly	Lilly
10	AbbVie (United States)	Teva	Teva	AbbVie

Source: PM Group, 2015, Top 25 pharma companies by global sales. PM Live, available at http://www.pmlive.com/top_pharma_list/global_revenues, accessed 1 November 2014.

A. Competition concerns in the public sector

11. Countries take measures to regulate prices in order to streamline expenses for pharmaceuticals and reduce drug prices in the public health care systems. Pharmaceutical

pricing practices and controls vary across countries. Where the products in a therapeutic class are close substitutes, the prices of the drugs in that class are often set equal to the lowest price in that class. Where a drug has few close substitutes, it is also common to set prices based on international price comparisons of equivalent drugs. Where a drug is covered by the list of vital and essential drugs,[4] procedures for the establishment of wholesale and retail trade markups and their maximum rate are strictly regulated. Some countries also regulate the prices and services of pharmaceutical wholesalers to keep a check on possible market manipulations. However, administrative regulation also can create competition concerns.

12. First, rigid price regulation has stabilized the prices of certain drugs, but reduced the availability of inexpensive alternatives to brand name drugs and increased the markups on unregulated medicines, as the wholesalers and retailers have shifted their lost profit to expensive unregulated drugs. For example, analyst agencies data for 2011 indicate that the average prices of drugs used for medical purposes rose by 8.8 per cent, in contrast to 10.8 per cent for drugs not covered by the model list of essential medicines, and a decrease of 3.3 per cent, for those drugs listed for medical use.[5]

13. Second, governments are notoriously inefficient buyers.[6] In some countries, government representatives entrusted with power to determine prices in negotiation with monopoly manufacturers might abuse that power for private gain, wasting public resources. A lack of accountability and transparency during tender and negotiation can provide a breeding ground for corruption, creating competition concerns. Corruption in public procurement could create an uneven playing field that affects competition.

14. Third, in some public health distribution systems, physicians influence drug sales, and patients are misled into purchasing more expensive medicines. Since only physicians have the right to issue prescriptions, while patients have no choice in medication, the practices of bribe and rebate – not price and quality – may determine which drugs are chosen. In some countries, corruption-related anticompetitive practices directly increase the price of medicines and restrict consumers' access to effective and affordable medicine. In India, for example, given the anticompetitive practices common to the health delivery system, only 35 per cent per cent of Indians have access to essential medicines.[7] Stakeholders in Tajikistan and Costa Rica contend that the lack of transparency contributes to the siphoning of public resources into a physician's private hospital or practices.[8]

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[4] Essential drugs, as defined by WHO, are "those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms, and at a price that individuals and the community can afford" (resolution WHA31.32). They are contained in the WHO Model List of Essential Medecines (eighteenth edition) of April 2013.

[5] See note 1.

[6] J Clark, 2005, Competition advocacy: Challenges for developing countries, *OECD Journal of Competition Law and Policy*, 6(4): 69–80, available at http://www.oecd-ilibrary.org/docserver/download/2404051ec003.pdf?expires=1429540476&id=id&accname=ocid57015274&checksum=F35EC94A2EDDF8D196B24D62017BF391, accessed 24 April 2015.

[7] CUTS Center for Competition, Investment and Economic Regulation, 2008, Dealing with anticompetitive practices in the Indian pharmaceuticals and the health delivery sector, Briefing Paper No. 5, available at http://www.cuts-international.org/pdf/CCIER-3-2008.pdf, accessed 20 April 2015.

[8] United Nations Development Programme, 2014, Building transparency, accountability and anti-corruption into the post-2015 development framework, Discussion Paper, available at http://workspace.unpan.org/sites/Internet/Documents/UNPAN93602.pdf, accessed 20 April 2015.

B. Competition concerns in the private sector

15. In the private sector, supply- and demand-side anticompetitive practices are prevalent.

16. On the supply side, typical horizontal agreements such as bid rigging, cartels and boycotts, are conventional tools that are used to fix prices and earn monopoly profits. Pay-for-delay agreements, a less conventional yet prevalent anticompetitive practice, deserve close attention from competition authorities. These agreements are common when a patent holder settles patent litigation by paying a generic pharmaceutical competitor to delay or abandon its plan to launch a competing drug. In 2010, the United States Federal Trade Commission estimated that pay-for-delay settlements cost American consumers $3.5 billion annually. As a result, United States competition agencies have repeatedly attacked this type of agreement in court, participated as amici in private actions and supported legislative efforts to curb such agreements.[9]

17. Regarding unilateral conduct by drug makers, patent owners' abuse of dominance raises major barriers to market entry for generic products. New drug developers argue that the research, development and marketing of new pharmaceutical products is very expensive and risky. Originator producers usually seek patent protection for their products, and variations thereof, for as long as possible and therefore have an incentive to restrict competition.

18. For many years, a brand company's main strategy for blocking or delaying generic companies was to refuse licensing or to charge unreasonably high royalties. For example, setting an unreasonable high royalty may be considered an implicit refusal to license. Competition-based licences authorize a person to exploit patents in order to market generic versions of patented medicines or dose combinations in return for payment of a reasonable royalty.[10] If access to medicines that are used to treat chronic illnesses or that constitute life-saving therapy is unreasonably restricted, particularly for illnesses affecting people living in poverty, some Governments will issue general public interest licences.

19. In recent years, originator companies have developed more sophisticated anticompetitive strategies to block or delay the development or market access of generic products, mainly by engaging in evergreening, product hopping and sham litigation.

20. Evergreening strategies help originator companies obtain the most efficient, broadest and longest possible patent protection for their products and variations. To ensure exclusivity, at least until the end of the base patent protection period, originator companies may file many patent applications on process, formulation and dosage regimes, which can be broad in both scope and claim. This is often referred to as a patent cluster. A divisional patent application is created where the applicant, either voluntarily or at the request of the examining office, divides a parent patent application into one or more narrower patent applications.[11]

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[9] OECD, 2014, Summary record of the Discussion on competition and generic pharmaceuticals, DAF/COMP/M (2014)2/ANN3, 6 November, available at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/M%282014%292/ANN3/FINAL&doclanguage=en, accessed 24 April 2015.

[10] SM Flynn, 2014, Using Competition Law to Promote Access to Medicines, https://www.wcl.american.edu/pijip/download.cfm?downloadfile=34080B0A-C32A-6A22-22ED8491FC3EB62B, accessed 27 April 2015.

[11] European Commission, 2008, Executive Summary of the Pharmaceutical Sector Inquiry Report, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf, accessed 20 April 2015.

21. The denser the patent cluster or divisional patent, the more difficult it will be for a generic company to bring its generic version of the original pharmaceutical product to the market. All generic manufacturers know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that their product will not infringe and thus become the subject of an interim injunction. That is to say, although the main patent protecting the product, for example the basic substance patent, may have expired, the generic version may still infringe one of the multiple patents surrounding the original pharmaceutical. This kind of patent application strategy serves to secure an optimal competitive position for originator companies' products in the market by creating significant legal and commercial uncertainty of viable generic entry to block competitors. Therefore, patent clusters and divisional patents seem to be aimed at creating legal uncertainty for generic competitors; nevertheless, they may signify an increase of incremental innovation. As for the enforcement efforts against this type of patent strategy, the decision of Italy's highest administrative court in the Pfizer case, outlined below, represents the most current development on this topic.

22. In some cases, patent clusters and divisional patents might be used as indispensable assets for originator companies to engage in patent litigation, which will create obstacles to market entry of generics, namely by creating costs and using injunctions preventing the sale of the generic product. While larger generic companies may have the financial resources to undertake long and costly litigation, smaller companies may be more substantially affected by increasing litigation costs. Interim injunctions prevent a small generic company from selling its product, whereas the originator company will continue to collect revenues from its product in the name of zero tolerance to any patent infringements.

23. Product hopping or product switching generally involves branded manufacturers introducing new formulations of patented drugs shortly before the patent protection on the older version of the drug expires, and then withdrawing the older drug that faces imminent generic competition. This conduct often allegedly involves the steering of physicians or pharmacists to "hop" demand over to the new branded drug formulation, which is protected by a long-term patent. As generic drugs tend to rely on substitution rules that allow pharmacies to swap the generic equivalent for a branded drug, when physicians stop writing prescriptions for the older drug, this eliminates the possibility of substitution and thus the possibility of meaningful generic competition.[12]

24. Mergers and acquisitions have been widespread in recent years. In the first half of 2014, the top 10 transactions totalled nearly $90 billion.[13] Historically, investment in research and development to generate a flow of new chemical entities has been the business model for pharmaceutical transnational corporations with headquarters in developed countries. However, several changes have taken place. First, many companies are facing soon-to-expire patents, comprising up to 70 per cent of some companies' total sales. Second, Indian, Chinese and Brazilian generic companies are growing rapidly, leading to a highly global competitive environment.[14] These changes lead to the demise of the research and development investment model, and a wave of mergers and acquisitions where large research and development-based transnational corporations are buying generic companies with potential new drug pipelines, such as Roche and Genentech, Sanofi Aventis and Genzyme, and Daichi Sankyo and Ranbaxy. Most developing world generic markets are

[12] GN Addy and E Douglas, 2014, Canada considers hopping on board with a product-hopping case, *Competition Policy International, Antitrust Chronicle Competition Policy*, Spring 2014, Vol. 3, No. 2.

[13] FiercePharma, 2014, Pharma's top 10 M&A deals of 2014's first half, 28 October, available at http://www.fiercepharma.com/special-reports/pharmas-top-10-ma-deals-2014s-first-half, accessed 20 April 2015.

[14] UNCTAD-International Centre for Trade and Sustainable Development, 2011, The structural changes in the global pharmaceutical marketplace and their possible implications for intellectual property, Policy Brief No. 10, July.

called branded generic markets, as the medicines carry a local brand name instead of the scientific generic name.

25. On the demand side, a significant role assumed by physicians in influencing drug sales in some countries has resulted in patients being misled into purchasing more expensive medicines. Activities involving inappropriate payments to hospitals and doctors have concerned regulators for many years. The pharmaceuticals, through rebates, unduly turned consumer (patient) benefits into the medical institution's proceeds.

26. In distribution chains, vertical restraints in supply and sales agreements to prevent retailers and wholesalers from obtaining supply from competitors are also fairly widespread. The Fair Trade Commission of the Republic of Korea found that 55 per cent of pharmaceutical supply and sales contract terms prevented buyers from dealing with possible rival products and imposed sales quotas in that country. Some clauses on no-rival product requirements were structured to outlast the contract itself. To address unfairness and improve consumer welfare, the Fair Trade Commission codified new guidelines for fair pharmaceutical transactions, which do not allow the following:

(a) Restrictions on research and development and production, as well as prohibitions on dealing with rival products after contract termination;

(b) Automatic contract terminations upon failure to reach a minimum purchase or sales quota;

(c) Unconditional transfers of technological innovations developed fully by a buyer, and allowing only exclusive raw material purchase in exceptional cases for product quality control. Moreover, horizontal agreements at the distribution level are also possible, as shown by recent action taken by the Brazilian competition authority.[15]

II. Case examples: How competition enforcement benefits consumers

27. In the pharmaceutical industry, competition policy benefits consumers in the form of increased accessibility to medicines at affordable prices, both in the public sector and on the commercial market. Competition enforcement benefits consumers by detecting, halting, and correcting anticompetitive practices. Table 2 gives examples of price reductions achieved through the use of competition enforcement in the industry.

[15] OECD, 2014, Competition issues in the distribution of pharmaceuticals: Contribution from the United States, DAF/COMP/GF/WD (2014) 43, 10 February.

Table 2
Examples of competition legal action in the pharmaceutical industry

Country and date of action	*Description of action*	*Pharmaceutical products*	*Impact*
France, 2013	Following complaint by Teva, French competition authority found Sanofi-Aventis had abused a dominant position with a strategy to denigrate generic versions of its branded drug, Plavix	Clopidogrel	Sanofi-Aventis fined €40.6 million.
European Union, 2012	European Court of Justice affirmed Commission findings of abuse of dominant position by AstraZeneca in providing misleading information to patent offices and deregistering product to inhibit generic entry	Losec	AstraZeneca fined €52.5 million
Colombia, 2009	Finding fewer than three homogenous products on the market, National Medicines Pricing Commission regulated price of medicine sold by Abbott Laboratories	Lopinavir and Ritonavir	Average price reduction ranging between 54 per cent and 68 per cent per person per year
Italy, 2007	Competition authority initiated investigation into abuse of dominant position by Merck	API Finastertide	Defendant agreed to grant free licences to allow manufacture and sale of API prior to expiration of patent term
South Africa, 2003	Competition Commission found two pharmaceutical companies guilty of excessive pricing and denying a competitor an essential facility, following complaints from activist groups	AZT, lamivudine and nevirapine and fixed-dose combinations containing these anti-retrovirals.	Led to voluntary settlement agreements with GlaxoSmithKline and Boehringerlngelheim providing licensing of patents to seven generic companies, based on 5 per cent royalties
United States, 2000	Federal Trade Commission charged generic producers with restraint of trade and conspiracy to monopolize markets for two generic drugs; settlement agreed	Lorazepam and Clorazepate	Lead defendant (Mylan) placed $100 million into escrow account for distribution to purchasers of relevant drugs during time period covered by settlement

Source: United Nations Development Programme, 2014, *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*, New York.

A. Competition enforcement against horizontal agreements

28. Measures employed against bid rigging in public procurement processes are a key tool of competition enforcement, especially in developing countries where government spending accounts for a higher percentage of GDP.

29. In May 2006, the Competition Commission of Mexico requested information from the Mexican Institute of Social Security (IMSS), the biggest health services provider in Latin America, regarding its bidding procedures for acquiring medicines. The material provided evinced the presence of collusion in the IMSS public procurement process. The investigation focused on public bidding from 2003 to 2006 for two specific products, human insulin and electrolytic solutions, and demonstrated constant communication between participating firms, particularly across the dates nearing the bids. Consequently, the Commission in 2010 fined six pharmaceutical companies 151.7 million pesos, a decision that was supported by the Mexican judiciary. Increased competition benefited consumers by average price falls: 68.1 per cent for human insulin and 12.1 per cent for electrolytic solutions.[16]

30. Another example of enforcement against horizontal anticompetitive agreements can be found in a Spanish boycott case. In 2007, Laboratorios DAVUR (DAVUR) filed a complaint against four pharmacy associations, claiming a collective boycott. DAVUR decided to lower the price of 12 of its generic pharmaceuticals to below the reference prices set by the Health Ministry. Subsequently, several pharmacy associations made recommendations to almost all pharmacies in Spain to stop stocking DAVUR medicines. These associations noted that, since DAVUR's lower prices could reduce the reference prices of generic medicines as set by the Health Ministry and thus decrease the associations' future revenues, those associations recommended the restriction of DAVUR's products. As a result, many Spanish pharmacists stopped dealing with DAVUR and impeded the entry of its products. During the investigation, DAVUR settled with the main claimants and withdrew its complaint. Nevertheless, the investigation continued ex officio. In March 2009, the Spanish competition authority resolved to declare the existence of an infringement and imposed a total fine of €1 million on the associations.[17]

31. The Actavis case in the United States and the Lundbeck case in the European Union represent the most recent enforcement trends in unconventional pay-for-delay agreements.

Box 1. Pay-for-delay cases in the United States and the European Union

In the *Federal Trade Commission v. Actavis*, Actavis, then Watson Pharmaceuticals, filed an abbreviated new drug application, seeking approval to market a generic drug modelled on a patented synthetic testosterone, AndroGel. The owner of the patent, Solvay Pharmaceuticals, filed suit against Actavis and others for patent infringement. In 2006, the parties entered into a settlement whereby Solvay (the patent owner) agreed to pay Actavis (the alleged infringer) $19 million to $30 million a year for nine years. Additionally, Actavis agreed to delay entry into the market until 31 August 2015, about five years before expiration of the patent. On 17 June 2013, the the United States Supreme Court held that the rule of reason would apply to reverse payment settlements.

Following the Actavis case, the European Commission fined the Danish pharmaceutical company Lundbeck €93.8 million for entering into reverse payment settlements with several generic producers (Alpharma, Arrow, Merck KGaA/Generics (United Kingdom) and Ranbaxy), which were also fined between €9.9 million and €21.4 million each. This was the first time the Commission had fined companies on the grounds that reverse payment settlements contravened European Union competition law.

[16] Contribution from Mexico to the UNCTAD round table on the benefits of competition policy for consumers, Intergovernmental Group of Experts on Competition Law and Policy, fourteenth session, Geneva, 8–10 July 2014.

[17] OECD, 2014, Competition issues in the distribution of pharmaceuticals: Contribution from Spain, DAF/COMP/GF/WD (2014) 47, 10 February.

In the Lundbeck case, the manufacturer of Citalopram, a "blockbuster" antidepressant medicine, held patents covering both the citalopram molecule and the process by which the molecule is manufactured. As the 2003 patent expiry date for the citalopram molecule approached, Lundbeck brought patent disputes against generic companies proposing to enter the market with generic versions of citalopram, for infringing its manufacturing process patent. The parties ultimately settled the disputes on terms that included significant payments by Lundbeck to generic companies. The Commission observed that once generic citalopram did enter the British market, prices dropped by 90 per cent on average. This reinforced its view that Lundbeck and the relevant generics were sharing monopoly rents among themselves.

Source: Ashurst Australia, 2013, EU [European Union] Commission issues first fines for "reverse payment" settlements, 25 June, available at www.ashurst.com/page.aspx?id_content=9268, accessed 21 April 2015.

32. In addition to agreements between suppliers, horizontal agreements at the retail level are also possible. In January 2014, the Administrative Council for Economic Defence of Brazil (CADE) ruled against a drugstore cartel in Curitibanos, a city located in Santa Catarina state, and imposed sanctions on all participating companies. The administrative process was started because a representation was sent to CADE by the Office of the Public Prosecutor. The alleged conduct consisted of agreements between drugstores to establish specific days of the week when each competitor would offer discounts. Therefore, CADE concluded that drugstores illegally colluded to establish a rational system of discounts and imposed fines amounting to R$1.5 million.[18]

B. Competition enforcement against vertical agreements

33. In distribution chains, vertical restraints in supply and sales agreements to prevent retailers and wholesalers from obtaining supply from competitors are also fairly common.

34. In France, Schering-Plough's patent for Subutex had expired. Three months before market entry by its generic competitor, Schering-Plough began offering large discounts, similar to loyalty discounts, to pharmacists on the sale of Subutex. The only purpose of these discounts was to prevent pharmacies from obtaining supply from the generic manufacturer. According to regulations in France, generic firms are allowed to offer much larger discounts (10.74 per cent) than originator firms (2.5 per cent). To bypass this regulation, Schering-Plough paid pharmacists for alleged services. The French competition authority determined, however, that the volume of granted discounts did not depend on the service pharmacists provided, but on the quantity of the purchased drugs. As a result, pharmacists obtained such a massive supply of Subutex that there was no room left for the generic version when it entered the market. In December 2013, the competition authority ruled that Schering-Plough had abused its dominant position through its discount strategy and imposed a €15.3 million fine on the company.[19]

35. In China, the National Development and Reform Commission found that two pharmaceutical companies, Shuntong and Huaxin, had signed exclusive distribution agreements with the only two domestic producers, allowing them to control the supply of promethazine hydrochloride, a key raw material for the compound reserpine, commonly used in high blood pressure treatments. These agreements required the producers to obtain

[18] Administrative Process No. 08012.004365/2010-66.

[19] See note 9.

approval from both companies before selling the product to any other party, in order to eliminate competition. In 2011, the Commission fined the companies RMB 7 million.[20]

C. Competition enforcement against unilateral conduct

36. Regarding refusal to license, a strategy employed for blocking entry of generic companies, several complaints were filed from 2002 to 2007 with the South African Competition Commission alleging the abuse by multinational pharmaceutical companies of intellectual property rights concerning drugs used to treat HIV/AIDS. These major branded pharmaceutical firms had failed to license their patents on reasonable terms to generic firms in a country where the targeted disease was a serious public health-care issue. Since the firms were willing to settle the case during the investigation, there was no need for a competition enforcement decision. Under the settlement, both companies agreed as follows:

(a) To grant licences to the generic firms;

(b) To permit the licensed firms to sell generic products in the region;

(c) To permit the licensed generic firms to mix the drugs so as to create better combinations for patients;

(d) Not to require royalties above 5 per cent of their net sales.

37. This settlement enabled generic competition and led to lower prices to the benefit of patients. A 2006 study showed that the price of one of the branded drugs to treat HIV/AIDS fell by more than 50 per cent between 2002 and 2006, while the generic equivalent was even cheaper.[21]

38. A recent decision on evergreening by an Italian court was key in developing the legal rule concerning the abuse of intellectual property rights, striking a balance between the rights of inventors and consumers through competition enforcement (see box 2).

39. An example of product hopping or product switching can be found in a recent case in the United Kingdom. Reckitt Benckiser, the multinational consumer goods company, marketed a drug called Gaviscon Original. After the patent expired but before a generic was introduced, Reckitt Benckiser launched a new version of the drug called Gaviscon Advanced. The company withdrew Gaviscon Original from the market and took measures to delay the introduction of a generic name.

40. In the United Kingdom, when the patent for a branded drug expires, the authorities introduce a generic name that doctors can apply to any generic equivalent of that drug. If the generic name is used on a prescription, the pharmacist is free to provide any appropriate drug, presumably the cheapest one. However, once a doctor prescribes a drug with a brand name, the pharmacist has to provide that drug, which cannot be substituted for a generic alternative. Reckitt Benckiser's strategy was set out in an internal e-mail, stating that "we should remind ourselves what our objective is here. To delay for as long as possible the introduction of a generic name and subsequent blacklisting of Gaviscon, while they cannibalize our existing franchise with Gaviscon Advanced". This is a fairly straightforward case, in which Reckitt Benckiser admitted liability early on and paid a fine.[22]

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[20] National Development and Reform Commission of China, 2011, available in Chinese only at http://xwzx.ndrc.gov.cn/mtfy/dfmt/201112/t20111207_449580.html, accessed 20 April 2015.

[21] See note 9.

[22] Ibid.

Box 2. Italy: The Administrative Supreme Court confirms the Italian competition authority's decision against evergreening

In 2012, the Italian competition authority sanctioned the multinational pharmaceutical group Pfizer, imposing a fine of €10,677,706. Pfizer's complex strategy consisted of several types of conduct, all proved and reasonably considered punishable by the competition authority. They included the following:

- The filing of divisional patent applications and the subsequent request of a Supplementary Protection Certificate, in order to extend the Italian patent protection many years after filing the main patent application, which still contained claims related to Latanoprost, and for which there was an absence of a commercial exploitation of a new product;
- Patent-related Court litigations hindering market entry of generic companies (shame litigation); (c) actions aimed at preventing the Italian Medicines Agency from granting geneticists marketing authorizations; and (d) application for a further patent protection extension through paediatric experimentation. All of these complex conducts, although individually and abstractly legitimate, could correctly be defined as abuse of rights and specifically anticompetitive. Pfizer refused to accept the penalty and brought administrative litigation to the Regional Administrative Court of Lazio, where the decision of the Competition Authority was annulled, as the Court held that Pfizer only tried to protect its legitimate interests, through types of conduct deemed lawful under patent law.

Following the Court's decision, the Competition Authority lodged an appeal before the Council of State, the highest administrative court on competition, against the decision of the Regional Administrative Court. The judge finished the reasoning of abuse by holding that such abuse of a dominant position belongs to the broader category of abuse of right. The doctrine of the abuse of rights includes the existence of a right; the possibility to effectively use such a right in different manners; the exercise of the right in a reprehensible manner, although formally legitimate; and the resulting unjustifiable disproportion between the benefit of the right's owner and the harm caused to the counterparty.

In other words, the abuse of rights does not suppose a formal infringement of laws, but the distorted exercise of the granted rights for purposes different from those intended by the legislator. Therefore, besides the legitimate nature of the right, the purpose to grant such legal right by the legislator shall be taken into account with more proportion when weighing the pros and cons in making a decision on the abuse of intellectual property rights. If the existence and exercise of industrial property rights are not of themselves incompatible with competition law, they are not immune from the application of competition law.

Source: C D'Amore, 2014, The administrative supreme court confirms the ICA's [Italian Competition Authority's] decision to condemn Pfizer for abuse of dominant position aimed at delaying the market entry of generic pharmaceutical companies, *Italian Antitrust Review*, 1:77–81.

D. Merger review

41. In the United States, some commentators have perceived tension between the Affordable Care Act and the antitrust laws in merger investigations since 2014. Partly due to the Act, which encourages provider integration, the health care sector has seen a significant consolidation. The Federal Trade Commission considers that the antitrust laws and the Act are compatible and that the goals of the latter are consistent with those of

competition policy. The Act seeks to promote higher quality care at lower cost through increased coordination and clinical integration. The Commission remains committed to its position that health care merger enforcement will continue to rely on traditional analytical approaches. In other words, it challenges the anticompetitive consolidation of hospitals or providers, but does not block collaborations where the evidence shows a transaction will result in lower costs, improved care and a net benefit to consumers.

42. In the pharmaceutical sector, merger enforcement has remained largely consistent in recent years. The Federal Trade Commission challenged the acquisition of Agila Specialties Global PteLtd and Agila Specialties Pvt Ltd. by Mylan, Inc. on 26 September 2013. It also adopted a final order in its challenge to the acquisition of Actavis, Inc. by Watson Pharmaceuticals on 14 December 2012. In both cases, the Commission required divestitures of various drugs to generic manufacturers based on its practice of defining relevant markets based on particular drugs, as opposed to courses of treatment for particular conditions. The Commission has been active in enforcement against 19 mergers in the branded and generic pharmaceutical sectors in the last five fiscal years.[23]

III. The role of competition policy

43. When competition policy acts beyond competition enforcement, it participates more broadly in the formulation of country's economic policies. In the pharmaceutical sector, competition advocacy acts proactively to lower entry barriers and promote competition. Through intervention in pre-grant and post-grant procedures relating to intellectual property, competition advocacy aims to strike a balance between the rights of inventors and consumers.

44. Another area in which competition policy can be especially helpful is public procurement, where procedures may invite collusion and corruption.[24] Successful advocacy in this area, along with working together with anti-corruption policies, will avoid the misuse of public funds and facilitate consumers' access to effective and affordable medication. Competition authorities may also help consumer empowerment through consumer education, facilitating consumer access to information and enhancing the capacity to correctly assess information to make optimal decisions. To conclude, competition policy is a crucial tool for building a transparent, anti-corruption, anti-monopoly and consumer-friendly environment. Coordination between competition authorities and other government agencies, such as consumer protection authorities and pharmaceutical sector regulators, will benefit consumers in the long term.

A. Striking a balance between the rights of inventors and consumers

45. Originator companies produce and sell pharmaceutical products developed during a research and development process deemed by drug companies to be lengthy and costly, and which involves substantial commercial risks. Brand drug companies contend that, on average, it takes 10–15 years to develop a medicine or vaccine. The research-based pharmaceutical industry maintains that it currently spends over $135 billion on research and development per year and that it costs an average of $1.38 billion to develop a single drug.[25] Brand drug companies argue that originator products are protected by intellectual property rights, in particular patent rights, because they give originator companies an

[23] See note 17.
[24] See note 6.
[25] Ibid.

opportunity to recoup investment costs and provide incentives for continued innovation.[26] This, the industry argues, makes important contributions to meeting patients' interests.[27]

46. In principle, generic companies produce and market an equivalent version of the original medicine once patent protection of that medicine has expired, inevitably resulting in a significant decline in price and market share of the original product. In the United States, the average price of generic drugs can be as much as 86 per cent less than that of their brand-name counterparts. In this context, competition concerns may arise when originator companies use their intellectual property rights to restrict or delay the market entry of generic medications.

47. The existence of a conflict between the rights of inventors and consumers depends on the balance between exclusiveness and public access.

48. Developed countries provide adequate protection to patent holders where domestic medicine manufacturing industries are competitive with proven invention capability, in order to maintain industry competitiveness in the global value chain.

49. In 2002, a decision by WTO members approved the delay of patent protection for least developed countries until 2021. Based on the weak invention capability of local drug makers, reverse engineering is allowed in order to encourage generic medication production.

50. For developing countries with pharmaceutical industries that have limited ability to make inventions, competition enforcement against generic pathway-related abuse is an important tool in promoting free access to health technologies. Therefore, where there is a conflict between competition and intellectual property policies, developing countries are inclined towards competition rather than exclusiveness. However, as the invention capability of domestic drug makers grows, a new balance will be needed.

51. Aside from the use of competition enforcement against abuse of dominance by originator companies, a toolbox has been designed for developing countries to shape the broad scope of exclusive rights before a patent is issued (pre-grant) and after a patent has been granted (post-grant), and thus ensure the accessibility of generic medications. This can be found in an UNCTAD reference guide for developing countries to use intellectual property rights to stimulate pharmaceutical production.[28]

52. Pre-grant flexibilities are a proactive tool that can be used by a Government to design and enforce intellectual property laws, such as employing a stricter standard of patentability criteria and patentable subject matter. In this context, competition advocacy is a useful tool for States to address competition concerns within existing patent systems and enact reforms not covered by the Agreement on Trade-Related Aspects of Intellectual Property Rights.

53. In 2014, South Africa began taking steps to achieve patent reform that would improve access to medicines and thereby strengthen the existing criteria for patentability. The current system allows pharmaceutical companies to obtain multiple patents on the same drug, even for inventions that do not fall under the country's definition of innovation. At present, the Competition and Consumer Policies branch of UNCTAD is assisting developing countries in striking a balance between intellectual property and competition

[26] See note 11.

[27] Ibid.

[28] UNCTAD, 2011, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide*, New York and Geneva, United Nations publication, available at http://unctad.org/en/pages/PublicationArchive.aspx?publicationid=437, accessed 20 April 2015.

policy by promoting the coordination between relevant authorities through joint capacity-building. This work started in October 2014 with projects with the Indonesian Government.

54. In Canada, the Competition Bureau may also intervene in Federal and Superior Court cases when it believes it is important to bring a competition perspective to proceedings that will not be brought by the parties. In other proceedings, when the Bureau believes that intellectual property rights could potentially be defined, strengthened or extended inappropriately, the Bureau may intervene to make representations concerning the scope of protection that should be accorded to intellectual property.

B. Cooperating with anti-corruption policies for good governance of public health resources

55. Given public health resource concerns, high levels of State-subsidized expenditures on pharmaceuticals provide sufficient motivation for all countries to make efforts to reduce drug prices. Centralized procurements and auction by tender are the most frequently used mechanisms. Successful advocacy in this area and cooperation with anti-corruption policies will avoid misuse of public funds and facilitate consumers' access to effective and affordable medication.

56. Collusion and corruption are distinct problems with public procurement; yet they may frequently occur in tandem and have mutually reinforcing effects. Collusion involves a horizontal relationship between public procurement bidders, and corruption occurs where public officials use public powers for personal gain.[29] Corruption is more prevalent in less competitive environments. By contrast, it is harder to offer bribes when many firms are competing in public procurement processes.[30] Well-designed procurement procedures can prevent collusion and corruption. In the European Union, all Member States must ensure that national measures to control prices of medicinal products or restrict the range of medicinal products covered by their national health insurance systems comply with the requirements of the Transparency Directive and the European Commission Treaty.

Box 3. Mexico: Cooperation between competition advocacy and anti-corruption

Examples from Mexico provide illustrations of competition enforcement against bid rigging in public procurement, which have benefited consumers by significant average price falls. The Mexican Competition Commission went beyond competition enforcement to engage in advocacy measures. To improve the design of the procurement procedures of IMSS, which were found to inhibit corruption and collusion, the Commission began advocacy by adopting of the OECD Guidelines to Fight Bid Rigging in Public Procurement. In recent years, the Commission has subscribed to several cooperation agreements with governmental authorities at all levels to facilitate the application of competition principles. All agreements include capacity-building on the prevention and detection of collusion and corruption, and the preparation of reports that provide recommendations to improve public procurement legislation, regulation and practices.

Source: OECD. 2014. Fighting corruption and promoting competition: Contribution from Mexico, DAF/COMP/GF/WD (2014) 50, 13 February.

57. Another relevant concern relating to competition is inappropriate payments by drug makers to hospitals and doctors in order to mislead consumers in public health distribution

[29] OECD. 2010. Round table on collusion and corruption in public procurement, DAF/COMP/GF (2010) 6, 15 October.

[30] OECD. 2014. Fighting corruption and promoting competition: Contribution from Mexico, DAF/COMP/GF/WD (2014) 50, 13 February.

systems. In some countries, physicians take on a significant role in influencing drug sales; as a result, patients are being misled into purchasing more expensive medicines. Since in some United Nations Member States commercial bribery is prohibited by competition law, competition policy can directly address corruption in the interest of consumers.

58. In 2011, the Fair Trade Commission of the Republic of Korea imposed corrective orders and surcharges of 11 billion won against six drug manufacturers for offering kickbacks. They repeatedly provided doctors, clinics and hospitals with economic incentives, through indirect means, to increase the prescription of their drugs. Such means included organizing seminars or conferences to offer free dinners, golf outings, and lecture and consultancy fees, or granting cash in the form of so-called post-market surveillance. Therefore, the pharmaceutical companies, through rebates, unduly turned consumer (patient) benefits into the medical institution's proceeds.

59. Similarly, in September 2014, the National Development and Reform Commission of China fined GlaxoSmithKline $490 million for bribery towards hospitals and doctors. Moreover, the Court issued a three-year suspended prison sentence to the former head of the company.

60. Sound policies and laws foster high ethical standards in both public and civil services. In addition to achievements of enforcement against specific restrictive business practices and advocacy for more efficient public procurement systems, competition policy can make further contributions to improved governance.

C. Coherence between competition, consumer and regulatory policies

61. The pharmaceutical industry is heavily regulated. All aspects of the life cycle of new drugs are regulated, from patent application to marketing approval, commercial exploitation, patent expiration and competition in the market, particularly with regard to generic drugs. Manufacturers, wholesalers, retailers, medical practitioners and stakeholders across the industry are subject to varying degrees of regulatory control aimed at ensuring product efficacy and safety. There is a need for coherence between competition policies and regulatory policies to enhance consumer welfare and economic efficiency.

62. In the United States, upon request of federal, state, or local government officials, the Federal Trade Commission helps legislators and regulators avoid consumer harm that would result from undue restriction of competition at each level of the pharmaceutical distribution chain. For example, the Commission has commented on direct-to-consumer advertising of prescription drugs from both consumer protection and competition perspectives. In this case, it suggested adjusting disclosure requirements to allow pharmaceutical manufacturers greater latitude in their advertising. By catalysing price and quality competition, net benefits of direct-to-consumer advertisements can be increased.[31]

63. Even with competition and a proper regulatory framework in place, consumers do not always choose the best options. Information asymmetries may contribute to this outcome. Moreover, making the wrong choice may adversely affect competition, resulting in a dysfunctional market where, despite effective competition but inadequate consumer protection, demand-side market failures may lead to consumer and structural detriment.

64. To benefit from competition, consumers must be empowered to activate it, which may be achieved through consumer education, as well as facilitating consumer access to information and enhancing the capacity of consumers to assess information correctly in order to make an optimal decision. Competition, regulatory and consumer policies should reinforce each other in achieving their common goals.

[31] See note 15.

65. In Chile, an agreement signed between the National Consumer Service, the health authority and the association of private clinics provides an example of a pro-competitive consumer policy intervention. The competition authority observed that patients were only provided with estimates of total costs, and price comparisons of different items included under treatment options were not possible, thereby leading to ex-post abusive billing by clinics. The competition authority conducted a market investigation and submitted its findings to the health authority, which took action. To address this market failure, the agreement requires clinics to inform patients of charges for medical services prior to treatment and ensures that price comparisons can be made by patients for different items. This case demonstrates the complementary nature of competition and consumer policies and the role of cooperation between relevant authorities in identifying appropriate remedies to address market failures in favour of consumers.[32]

Box 4. China: Pharmaceutical price liberalization

In China, the Government is accelerating the reform of pharmaceutical prices, the principal component of which is introducing competition. Over the years, maximum resale price maintenance has been adopted to control the drug prices. However, this method has failed to resolve issues relating to both high and low prices. In May 2014, the Department of Price Supervision of the National Development and Reform Commission announced the abolition of maximum resale price maintenance applicable to inexpensive drugs. Moreover, in accordance with the draft pharmaceutical price liberalization programme, the competition mechanism will gradually play a decisive role in resource allocation in the pharmaceutical sector. Aside from non-prescription drugs, prices of patented medicines and some heavily regulated products, including immunization, psychotropic medicines, narcotic drugs and blood products, will be liberalized initially. Ex post facto measures, such as anti-monopoly enforcement, will be strengthened to replace the price control measures by the regulator.

Source: xkb.com.cn, 2014, More radical price reform, 6 November, available in Chinese only at http://news.xkb.com.cn/caijing/2014/1106/358347.html, accessed on 20 December 2014.

IV. Issues for discussion

66. The following issues may be considered for discussion:

(a) What are the latest strategies adopted by pharmaceutical companies to stifle competition?

(b) Are there any types of unilateral conduct by producers that affect competition? In relation to this, what is the theory of "abuse of right"? How is an anticompetitive practice recognized? Is the assessment of such agreements conducted under a per se approach or the rule of reason approach?

(c) Are there anticompetitive agreements that affect competition between originator and generic drugs? In relation to this, what is the theory of harm? How is an anticompetitive practice recognized? For example, does it depend on the amount of the transaction? What happens if there is no financial transaction related to the agreement? Are such agreements always anticompetitive? Is the assessment of such agreements conducted under a per se approach or the rule of reason approach?

(d) Are there any vertical agreements at the distribution level, for example, exclusive distribution or loyalty discounts? What are the main characteristics of these

[32] TD/B/C.I/CLP/27.

agreements? Are there concerns that these agreements may reduce inter and intra brand competition? Are wholesalers vertically integrated with retailers and/or manufacturers? Are there concerns that vertical integration may reduce inter and intra brand competition?

(e) How can the objective of ensuring an adequate and affordable supply of drugs be better achieved by using competition advocacy?